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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/336,091	06/18/1999	JACQUES VAN SNICK	L0461/7063-J	7247

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EXAMINER
SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/336,091	VAN SNICK ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,5,7,9,14,76-79 and 81-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,5,7,9,14,76-79,81-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 2,5,7,9,14,76-79,81-83 are under consideration.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 5,14,78,83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the claimed inventions. Claims 2 and 9 (from which the rejected claims depend) recite a HLA DRB1*15 binding peptide that consists of SEQ. ID. NO:7 with 0-11 amino acids added at either or both ends. Therefore, claims 5,14,78,83 encompass use of a endosomal targeting peptide of 2-11 amino acids because the endosomal targeting peptide would only be attached to one end of the HLA DRB1*15 binding peptide and the endosomal targeting peptide attached to SEQ. ID. NO:7 can be only 2-11 amino acids. There is no disclosure in the specification as originally filed of use of an endosomal targeting peptide of 2-11 amino acids in length or use of such a peptide derived from the peptides of claims 78,83. There is no written description of the scope of the claimed inventions in the specification as originally filed (eg. the claimed inventions constitute new matter).

Regarding applicants comments, the amended claims still depend from claims 2 and 9 which recite a HLA DRB1*15 binding peptide that consists of SEQ. ID. NO:7 with 0-11 amino acids added at either or both ends. Therefore, claims 5,14,78,83 encompass use of a endosomal targeting peptide of 2-11 amino acids because the endosomal targeting peptide would only be attached to one end of the HLA DRB1*15 binding peptide and the endosomal targeting peptide attached to SEQ. ID. NO:7 can be only 2-11 amino acids. There is no disclosure in the specification as originally filed of use of an endosomal targeting peptide of 2-11 amino acids in length or use of such a

peptide derived from the peptides of claims 78,83. The addition of the term "further" does not change the dependency on claims 2/9.

It is suggested that this issue could be addressed with a separate independent claim indicating that the peptide contains two components wherein one is of the size recited in clam 2/9 and that it also has the pertinent endosomal targeting signal (using language supported in the specification as originally filed).

4. Claims 5,14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of the claimed invention.

Claims 5,14 encompass a peptide that contains an endosomal targeting signal. However, the only endosomal targeting signal disclosed in the specification are endosomal targeting portions of human invariant chain Ii or LAMP-1. The claims encompass use of a vast genus of potential agents which could function as an "endosomal targeting signal" while the specification only discloses endosomal targeting portions of human invariant chain Ii or LAMP-1 which have that function. The claims could potentially encompass the use of mutants or alleles of the aformentioned molecules or mimotopes with the functional properties recited in the claim or molecules with no structural relationship to the endosomal targeting portions of human invariant chain Ii or LAMP-1, but there is no disclosure of such agents in the specification and such molecules do not appear to be disclosed in the prior art. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed

herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. In the instant case, the facts are similar to those disclosed in University of California v. Eli Lilly and Co. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

5. The rejection of claims 2,9,81 under 35 U.S.C. 102(b) as being anticipated by Fikes et al. (WO 95/04542) for the reasons elaborated in the previous Office action is withdrawn in view of the amended claims and applicants arguments. The withdrawn rejection (as elaborated in the previous Office Action) referred to different teachings in

the Fikes et al. reference than those now utilized in the rejection presented in this Office Action.

6. The rejection of claims 2,7,9,79,81 under 35 U.S.C. 103(a) as being unpatentable over Fikes et al. (WO 95/04542) in view of Gelder et al. (US Patent 6,043,347) for the reasons elaborated in the previous Office action is withdrawn in view of the amended claims and applicants arguments. The withdrawn rejection (as elaborated in the previous Office Action) referred to different teachings in

the Fikes et al. reference than those now utilized in the rejection presented in this Office Action.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 2,9,76,77,81,82 are rejected under 35 U.S.C. 102(b) as being anticipated by Fikes et al. (WO 95/04542).

Fikes et al. teach a peptide that contains all of the amino acids of SEQ. ID. No. 7 except the first and last amino acids (see claim 4, Seq. Id. No. 15). Said peptide is derived from MAGE A1 (alias MAGE 1). The additional amino acid residues found in SEQ. ID. No.7 are residues found in the native MAGE A1 molecule. Fikes et al. teach that the peptide can be optionally flanked by additional MAGE 1 amino acids at both ends(see page 5, penultimate paragraph). Fikes et al. teach that the peptides are less than 15 amino acids (see page 5, last paragraph). Fikes et al. teach that the peptides are about 11 residues, which would encompass a 12mer peptide (see page 5, last paragraph). A 12mer peptide including SEQ. ID. No. 15 of Fikes et al. with additional MAGE 1 residues at both ends is the peptide recited in claim 2/76/77. Regarding claim 2, a 12mer or 13mer or 14mer including SEQ. ID. No. 15 of Fikes et al. with additional MAGE 1 residues at both ends is encompassed by the peptide recited in claim 2. Regarding claim 76, a 12mer or 13mer including SEQ. ID. No. 15 of Fikes et al. with

additional MAGE 1 residues at both ends is encompassed by the peptide recited in claim 76.

The MPEP section 2131.02 states:

A GENERIC CHEMICAL FORMULA WILL ANTICIPATE A CLAIMED SPECIES COVERED BY THE FORMULA WHEN THE SPECIES CAN BE "AT ONCE ENVISAGED" FROM THE FORMULA

When the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged." One may look to the preferred embodiments to determine which compounds can be anticipated. In re Petering, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

In In re Petering, the prior art disclosed a generic chemical formula "wherein X, Y, Z, P, and R'- represent either hydrogen or alkyl radicals, R a side chain containing an OH group." The court held that this formula, without more, could not anticipate a claim to 7-methyl-9-[d, l'-ribityl]-isoalloxazine because the generic formula encompassed a vast number and perhaps even an infinite number of compounds. However, the reference also disclosed preferred substituents for X, Y, Z, R, and R' as follows: where X, P, and R' are hydrogen, where Y and Z may be hydrogen or methyl, and where R is one of eight specific isoalloxazines. The court determined that this more limited generic class consisted of about 20 compounds. The limited number of compounds covered by the preferred formula in combination with the fact that the number of substituents was low at each site, the ring positions were limited, and there was a large unchanging structural nucleus, resulted in a finding that the reference sufficiently described "each of the various permutations here involved as fully as if he had drawn each structural formula or

had written each name." The claimed compound was 1 of these 20 compounds. Therefore, the reference "described" the claimed compound and the reference anticipated the claims.
In In re Schauman, 572 F.2d 312, 197 USPQ 5 (CCPA 1978), claims to a specific compound were anticipated because the prior art taught a generic formula embracing a limited number of compounds closely related to each other in structure and the properties possessed by the compound class of the prior art was that disclosed for the claimed compound. The broad generic formula seemed to describe an infinite number of compounds but claim 1 was limited to a structure with only one variable substituent R. This substituent was limited to low alkyl radicals. One of ordinary skill in the art would at once envisage the subject matter within claim 1 of the reference.).

The claimed peptides are immediately envisaged by the aformentioned teachings of the Fikes et al. reference. The aforementioned peptides would bind inherently bind HLA DRB*15 because they are the peptides recited in the claims. Fikes et al. teach MAGE 1 peptide compositions containing a MAGE 1 class binding peptide and a MAGE 1 class II binding peptide (see page 12, last paragraph) . In the instant rejection, the MAGE 1 class I binding peptide would function to bind HLA DRB1*15 (because it has the sequence recited in the claim) whilst the T helper epitope disclosed in page 12, last paragraph would bind MHC class I. There are hundreds of different MHC class I alleles that would bind largely discrete and nonoverlapping subsets of MAGE 1 derived peptides, wherein it would be reasonable to conclude that at least a fraction of said alleles could bind a T helper MAGE 1 epitope as per disclosed in page 12, last paragraph.

9. Claims 2,7,9,76,77,79,81,82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fikes et al. in view of Gelder et al. (US Patent 6,043,347).
Fikes et al. teach a peptide that contains all of the amino acids of SEQ. ID. No. 7 except the first and last amino acids (see claim 4, Seq. Id. No. 15). Said peptide is derived from MAGE A1 (alias MAGE 1). The additional amino acid residues found in SEQ. ID. No.7 are residues found in the native MAGE A1 molecule. Fikes et al. teach that the peptide can be optionally flanked by additional MAGE 1 amino acids at both ends(see page 5, penultimate paragraph). Fikes et al. teach that the peptides are less than 15

amino acids (see page 5, last paragraph). Fikes et al. teach that the peptides are about 11 residues, which would encompass a 12mer peptide (see page 5, last paragraph). A 12mer peptide including SEQ. ID. No. 15 of Fikes et al. with additional MAGE 1 residues at both ends is the peptide recited in claim 2/76/77. Regarding claim 2, a 12mer or 13mer or 14mer including SEQ. ID. No. 15 of Fikes et al. with additional MAGE 1 residues at both ends is encompassed by the peptide recited in claim 2. Regarding claim 76, a 12mer or 13mer including SEQ. ID. No. 15 of Fikes et al. with additional MAGE 1 residues at both ends is encompassed by the peptide recited in claim 76. Fikes et al. teach MAGE 1 peptide compositions containing a MAGE 1 class binding peptide and a MAGE 1 class II binding peptide (see page 12, last paragraph) . In the instant rejection, the MAGE 1 class I binding peptide would function to bind HLA DRB1*15 (because it has the sequence recited in the claim) whilst the T helper epitope disclosed in page 12, last paragraph would bind MHC class I. There are hundreds of different MHC class I alleles that would bind largely discrete and nonoverlapping subsets of MAGE 1 derived peptides, wherein it would be reasonable to conclude that at least a fraction of said alleles could bind a T helper MAGE 1 epitope as per disclosed in page 12, last paragraph.

Fikes et al. do not teach said peptide containing D-amino acids. Gelder et al. teach modified peptides containing D-amino acids (see column 20) and that such peptides have increased stability (see column 20). Said peptides would also be non-hydrolyzable because D-amino acid modified peptides have this property (eg. see claim 7 upon which claim 79 depends). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Fikes et al. teach the claimed peptide except for D-amino acid modification, while Gelder et al. teach modified peptides containing D-amino acids (see column 20) and that such peptides exhibit increased stability. One of ordinary skill in the art would have been motivate to do the aforementioned because Gelder et al. that teach modified peptides containing D-amino acids have increased stability.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 2720841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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